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Special 510k Summary: Bed-to-Bed Remote View for the Envoy Patient Monitor

- **Description of New feature**

The Bed-to-Bed Remote View feature of the Envoy Multiparameter Patient Monitor allows the Envoy to temporarily look at the display of another (remote) Envoy monitor while maintaining its current (local) monitoring capabilities. The Bed-to-Bed Remote View feature is an extension to the local monitoring capabilities of the Envoy monitor. Remote view includes a message display indicating the local bed (monitor and patient) being viewed and the remote bed (monitor and patient) being viewed. The remote display is maintained in a one-to-one format as it appears on the remote Envoy. Visual/audio Alarm indication of the remote Envoy are displayed, as well as up to 6 waveforms/vital signs from the remote site. In addition, the full screen of the remote view can be outputted on a printer and the ECG waveform can be outputted on an external recorder. All signal acquisition, processing and alarm determination is handled by Envoy in the same manner as under the original application.

- **Envoy Intended Use**

The intended use of the Envoy remains the same as the predicate Envoy 510(k) approvals – K974510 and K983864.

- **Proposed Labeling**

Proposed labeling includes modification to:

1. Envoy Operating Manual (see Section on Bed-to-Bed Remote View from the Envoy Operating Manual in Part 3) and to:

2. Promotional literature in order to include the Bed-to-Bed Remote View of the Envoy.

- **Parameters Displayed** - The Section from the Envoy Operating Manual on Bed-to-Bed Remote View (Part 3) shows examples of how the remote Envoy display is represented on the local Envoy. Parameters displayed include visual/audio Alarm indication of the remote Envoy, as well as up to 6 waveforms/vital signs from the Remote Site.

- **Design Control Activities**

Risk Analysis methods used and the results of the Risk Analysis

The Risk Analysis in Part 7 defines four categories of risks for Bed-to-Bed Remote View:

(a) possible user mistake as to the display being viewed on the Envoy monitor (i.e. local vs remote)
(b) limitation as to the number of parameters that are able to be displayed for the local bed
(c) long term use vs short term use
(d) remote "silencing" or setting of "alarms off".

Elimination or Reduction of possible Hazards

a) The display has been ergodynamically designed to assist user viewing. The display is sectioned into two separate panels:
- the upper panel contains the "local" monitoring display. Identification labeling at the top of the panel identifies the local bed's device name and patient name.
- the middle panel contains the "remote view" display. Identification labeling at the top of the panel identifies the remote bed's device name, patient name.

b) The number of parameters that the Envoy is able to display for the local bed is compromised while remote view is in action. Design of the remote view feature is such that it ensures that all local alarm messages are registered and displayed according to priority. The local ECG waveform (and measured values) displayed is the top most waveform in the hierarchical setting for ECG.

c) The bed-to-bed remote view is intended for temporary viewing of a remote bed. Return to full local patient monitor is performed by a single pushing of a single button – called "Main Screen". The Envoy Operating Manual (see page 10-14 in Part 3 of this submittal) clearly indicates that the bed-to-bed remote view feature is intended for temporary viewing only and is to be performed under the direct supervision of the user. An automatic (selectable) time out period is present, whereby the monitor automatically reverts to full Local display when the period is exceeded.

d) Remote setting of alarms off has a number of features built in to ensure safety. If alarm "Silence" is selected, then a 2 minute time out period automatically restores the alarms. When exiting Remote View, the remote bed alarm settings automatically revert to their "original settings", to ensure that the Remote bed remains with its original alarm settings.

- **Verification and Validation Activities**

Summary of Validation - Device validation studies were performed to verify that conditions displayed on the "local bedside device" were completely and accurately reported and displayed on the "Remote View" of the Envoy.

Software Verification, Validation and Testing :

The Envoy Bed-to-Bed Remote View Feature was tested according to Mennen Test Description as set out in Part 6. The Test Report is presented in Part 6.

Simulated inputs were used to test the vital signs monitored by the Envoy. The objective of this study was to compare the performance of the local Envoy against the performance of remote Envoy.

Software validation was tested against Mennen Medical's test plan protocol as presented in Part 6. Simulated patient waveforms were generated using a DNI Navada Inc. 217A Patient simulator.

Software Validation

Software validation verified the functionality of the Mennen Medical Envoy Bed-to-Bed Remote View from a "black box" approach. Validation was performed by persons other than those involved in the design of the system. This independent audit confirmed that the system software met the specified requirements.

Software Validation Plan:

The Software Validation plan tested the following areas:

Verified that the system performed according to specified requirements.

Verified the system by exercising user input and assuring correct output.

Checked for hidden functionality.

Verified that the system recovers from errors.

The Software Validation Plan was approved by Mennen Medical's Engineering and Quality Assurance Departments, ensuring that the tests were both valid and thorough. The Test Report was analyzed by the Quality Assurance and Engineering Departments. The results met expectations and the software was approved for release, pending clearance of the 510(k) submittal.

Conclusions Drawn from Validation Studies:

The results of the validation studies indicate that Envoy Bed-to-Bed Remote View is safe, effective and poses no new risks to the user and or patient.

- **Voluntary Standards**

  Appropriate voluntary standards for this device, to which conformance has been demonstrated – None.

- **EMI/RFI Test Results**

Remain the same as the Test Results enclosed in the 510(k) submittals of the Envoy (K974510 and K983864).

- **Indications for Use**

See page 5 (below) for the Indications for Use.

Note that original Indications for Use of the Envoy Patient Monitor (K974510) were amended in K983864 (approved on October 8, 1999) in order to include the EtCO2 module.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2000

Mr. Kenneth Raichman
Director of Regulatory Afafairs
Kiryat Weizmann Science Park
P.O.B 102
Rehovot 76100
ISRAEL

Re: K000563
Modification to Envoy Patient Monitor
Regulatory Class:..III (three)
Product Code: .74 MHX
Dated: April 13, 2000
Received:..April 18, 2000

Dear Mr. Raichman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

The ENVOY Monitor is a physiological patient monitor intended to be used for monitoring vital signs of critically ill adult and pediatric patients in the hospital environment, such as: ECG/Heart Rate, Invasive Blood Pressure, Respiration, Temperature, Noninvasive Blood Pressure, Pulse Oximetry and EtCO2.

The ENVOY may be used to monitor a wide range of patient conditions in many different clinical specialties within the hospital. The device is intended for use by qualified health care providers, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

for Mark N Milhorn

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000563